

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: DIET DRUGS (PHENTERMINE/ FENFLURAMINE/DEXFENFLURAMINE) PRODUCTS LIABILITY LITIGATION)))))	MDL NO. 1203
THIS DOCUMENT RELATES TO:)))	
SHEILA BROWN, et al.)))	CIVIL ACTION NO. 99-20593
v.)))	
AMERICAN HOME PRODUCTS CORPORATION)))	2:16 MD 1203

MEMORANDUM IN SUPPORT OF SEPARATE PRETRIAL ORDER NO. 8822

Bartle, J.

February 22, 2012

Roberta Haberman ("Ms. Haberman" or "claimant"), a class member under the Diet Drug Nationwide Class Action Settlement Agreement ("Settlement Agreement") with Wyeth,¹ seeks benefits from the AHP Settlement Trust ("Trust").² Based on the record developed in the show cause process, we must determine whether claimant has demonstrated a reasonable medical basis to support her claim for Matrix Compensation Benefits ("Matrix Benefits").³

1. Prior to March 11, 2002, Wyeth was known as American Home Products Corporation.

2. Sam Haberman, Ms. Haberman's spouse, also has submitted a derivative claim for benefits.

3. Matrix Benefits are paid according to two benefit matrices (Matrix "A" and Matrix "B"), which generally classify claimants for compensation purposes based upon the severity of their

(continued...)

To seek Matrix Benefits, a claimant must first submit a completed Green Form to the Trust. The Green Form consists of three parts. The claimant or the claimant's representative completes Part I of the Green Form. Part II is completed by the claimant's attesting physician, who must answer a series of questions concerning the claimant's medical condition that correlate to the Matrix criteria set forth in the Settlement Agreement. Finally, claimant's attorney must complete Part III if claimant is represented.

In February, 2010, claimant submitted a completed Green Form to the Trust signed by her attesting physician, Manoj R. Muttreja, M.D. Based on an echocardiogram dated February 24, 2002,⁴ Dr. Muttreja attested in Part II of Ms. Haberman's Green Form that she suffered from moderate mitral regurgitation. In addition, Dr. Muttreja represented that

3. (...continued)
medical conditions, their ages when they are diagnosed, and the presence of other medical conditions that also may have caused or contributed to a claimant's valvular heart disease ("VHD"). See Settlement Agreement §§ IV.B.2.b. & IV.B.2.d.(1)-(2). Matrix A-1 describes the compensation available to Diet Drug Recipients with serious VHD who took the drugs for 61 days or longer and who did not have any of the alternative causes of VHD that made the B matrices applicable. In contrast, Matrix B-1 outlines the compensation available to Diet Drug Recipients with serious VHD who were registered as having only mild mitral regurgitation by the close of the Screening Period or who took the drugs for 60 days or less or who had factors that would make it difficult for them to prove that their VHD was caused solely by the use of these Diet Drugs.

4. Although the Green Form indicates a date of February 24, 2002, the report of claimant's echocardiogram indicates that it was performed on February 23, 2002.

claimant had surgery to repair or replace her mitral valve.⁵ Based on such findings, claimant would be entitled to Matrix A-1, Level III benefits in the amount of \$335,553.⁶

In the report of claimant's echocardiogram, the reviewing cardiologist, Linda J. Crouse, M.D., F.A.C.C., noted that the anterior and posterior leaflets of claimant's mitral valve were thickened. Dr. Muttreja, however, attested in claimant's Green Form that Ms. Haberman did not suffer from mitral annular calcification. Under the Settlement Agreement, the presence of mitral annular calcification requires the payment of reduced Matrix Benefits. See Settlement Agreement § IV.B.2.d.(2)(c)ii)d). As the Trust does not contest Ms. Haberman's entitlement to Level III benefits, the only issue before us is whether claimant is entitled to payment on Matrix A-1 or Matrix B-1.⁷

5. Dr. Muttreja also attested that claimant suffered from mild aortic regurgitation, aortic sclerosis, and an abnormal left atrial dimension and that claimant had aortic valve surgery. These conditions are not at issue in this claim.

6. Under the Settlement Agreement, a claimant is entitled to Level III benefits if he or she suffers from "left sided valvular heart disease requiring ... [s]urgery to repair or replace the aortic and/or mitral valve(s) following the use of Pondimin® and/or Redux™." Settlement Agreement § IV.B.2.c.(3)(a).

7. Ms. Haberman previously received Seventh Amendment Category One Benefits in the amount of \$122,687.57. If Ms. Haberman's supplemental claim for Level III benefits is payable only on Matrix B-1, Ms. Haberman will not receive any additional payment because the amount to which she would be entitled for her Matrix B-1, Level III claim is less than the amount she already received under the Seventh Amendment. See Settlement Agreement § IV.C.3.;
(continued...)

In May, 2010, the Trust forwarded the claim for review by M. Michele Penkala, M.D., one of its auditing cardiologists. In audit, Dr. Penkala concluded that there was no reasonable medical basis for Dr. Muttreja's finding that claimant did not have mitral annular calcification. In support of this conclusion, Dr. Penkala stated, "it appears that some [mitral annular calcification] is indeed present on this echo[cardiogram] study as well as the subsequent studies. In addition, there is calcification noted on the mitral valve leaflets themselves. The finding was also described on the intraop[erative] [transesophageal echocardiogram] dated [November 9, 2009]."

Based on Dr. Penkala's finding, the Trust issued a post-audit determination that Ms. Haberman was entitled only to Matrix B-1, Level III benefits. Pursuant to the Rules for the Audit of Matrix Compensation Claims ("Audit Rules"), claimant contested this adverse determination.⁸ In contest, claimant argued that Dr. Penkala's subjective opinion was inconsistent with the unanimous opinions of at least four other physicians, and that Dr. Penkala was neither qualified to serve as an

7. (...continued)
Seventh Amendment § IX.A.2.

8. Claims placed into audit on or before December 1, 2002 are governed by the Policies and Procedures for Audit and Disposition of Matrix Compensation Claims in Audit, as approved in Pretrial Order ("PTO") No. 2457 (May 31, 2002). Claims placed into audit after December 1, 2002 are governed by the Audit Rules, as approved in PTO No. 2807 (Mar. 26, 2003). There is no dispute that the Audit Rules contained in PTO No. 2807 apply to Ms. Haberman's claim.

auditing cardiologist nor independent from the Trust. Claimant also asserted that Dr. Penkala relied on irrelevant echocardiogram studies, including the intraoperative transesophageal echocardiogram of November 9, 2009.

Ms. Haberman conceded that she developed mitral annular calcification prior to undergoing heart valve surgery on November 9, 2009. She contended, however, that her eligibility for Matrix A benefits should be determined based on her earlier claim, and not her supplemental claim for Matrix Benefits. According to Ms. Haberman, her mitral annular calcification cannot be the cause of her mitral regurgitation or need for mitral valve surgery because she developed it after she developed mitral regurgitation. Thus, under the Settlement Agreement and the Seventh Amendment, she says, her claim should not be reduced.

Ms. Haberman has provided the declarations of Michael E. Staab, M.D., F.A.C.C., Dr. Muttreja, and Paul W. Dlabal, M.D., F.A.C.P., F.A.C.C., F.A.H.A., all of whom stated that claimant's February, 2002 echocardiogram did not demonstrate mitral annular calcification. Dr. Muttreja and Dr. Dlabal also submitted that Ms. Haberman's subsequent development of mitral annular calcification did not cause her mitral valve disease nor did it result in her need for surgery.

Although not required to do so, the Trust forwarded the claim to the auditing cardiologist for a second review. Dr. Penkala again concluded there was no reasonable medical basis for the attesting physician's finding that Ms. Haberman did not

suffer from mitral annular calcification. Dr. Penkala stated in her declaration,

10. I also find that Claimant's Contest Materials fail to demonstrate a reasonable medical basis for the Attesting Physician's representation the Claimant did not have mitral annular calcification. The 2/24/02 study is of poor quality, however upon review at Contest I found that [mitral annular calcification] is clearly present in the apical views.
11. [Mitral annular calcification] is even more evident on the later studies dated 5/3/07, 6/30/08, and 10/26/09. [Mitral annular calcification] is clearly seen in multiple views on the 5/3/07 study, and is also described by the reading cardiologist on this study (Dr. Michael S. Weinblatt of The Greater Fort Lauderdale Heart Group) who notes that "the mitral annulus is calcified." (See 5/3/07 Echocardiogram Report.)
12. [Mitral annular calcification] is also described on the report of echocardiogram studies dated 6/30/08, 3/31/09, and 10/26/09, as well as the intraop[erative] [transesophageal echocardiogram] dated 11/9/09. I note that Claimant's physicians, Dr. Muttreja and Dr. Dlabal concede that the claimant developed [mitral annular calcification] prior to heart valve surgery.

The Trust then issued a final post-audit determination, again determining that Ms. Haberman was entitled only to Matrix B-1, Level III benefits. Claimant disputed this final determination and requested that the claim proceed to the show cause process established in the Settlement Agreement. See Settlement Agreement § VI.E.7.; PTO No. 2807; Audit Rule 18(c). The Trust then applied to the court for issuance of an Order to

show cause why Ms. Haberman's claim should be paid. On December 20, 2010, we issued an Order to show cause and referred the matter to the Special Master for further proceedings. See PTO No. 8576 (Dec. 20, 2010).

Once the matter was referred to the Special Master, the Trust submitted its statement of the case and supporting documentation. Claimant then served a response upon the Special Master. The Trust provided a reply on March 14, 2011 and claimant a sur-reply on April 11, 2011. The Show Cause Record is now before the court for final determination. See id. at Rule 35.

The issue presented for resolution of this claim is whether claimant has met her burden in proving that there is a reasonable medical basis for the attesting physician's finding that she did not have mitral annular calcification. See id. Rule 24. Ultimately, if we determine that there is no reasonable medical basis for the answer in claimant's Green Form that is at issue, we must affirm the Trust's final determination and may grant such other relief as deemed appropriate. See id. Rule 38(a). If, on the other hand, we determine that there is a reasonable medical basis for the answer, we must enter an Order directing the Trust to pay the claim in accordance with the Settlement Agreement. See id. Rule 38(b).

In support of her claim, Ms. Haberman first asserts that there is a reasonable medical basis for her claim because her February, 2002 echocardiogram demonstrates the absence of

mitral annular calcification. In addition, Ms. Haberman reasserts her concerns with regard to Dr. Penkala's qualifications and independence.⁹

After reviewing the entire show cause record, we find claimant's arguments are without merit. As an initial matter, claimant does not dispute that she developed mitral annular calcification prior to her November 9, 2009 heart valve surgery. In fact, the reports of claimant's echocardiograms and the declarations of her own physicians confirm the presence of mitral annular calcification. For example, in his declaration, Dr. Staab stated:

4. On the 5/03/07 study, I found two bright spots around the mitral annulus, which might indicate the onset of [mitral annular calcification]. In my opinion, this finding was not clinically significant.

....

6. I did not unequivocally find [mitral annular calcification] until I reviewed the echocardiogram study dated 10/26/09.

9. Ms. Haberman also argues that she is entitled to Matrix A-1, Level III benefits because Dr. Penkala determined there was no reasonable medical basis for the attesting physician's representation that claimant has aortic sclerosis, a reduction factor for Matrix claims involving the aortic valve. See Settlement Agreement § IV.B.2.d.(2)(c)i)c). Dr. Penkala, however, explained in the Report of Auditing Cardiologist Opinions Concerning Green Form Questions at Issue that there was aortic sclerosis and that she "actually indicated 'yes' to this question," even though the form indicated "no." In any event, as Ms. Haberman's own physicians, including the attesting physician on the Green Form, concede the presence of aortic sclerosis, there is no basis for her claim that she is entitled to Matrix A-1, Level III benefits based on her aortic valve surgery.

In addition, Dr. Muttreja and Dr. Dlabal acknowledge that claimant developed mitral annular calcification prior to her valve surgery in November, 2009.

We disagree with claimant that the presence of mitral annular calcification at the time she qualified for Level III Matrix Benefits is irrelevant. To avoid receiving reduced Matrix Benefits, claimant must demonstrate, at a minimum, that she did not suffer from a reduction factor at the time she suffered from the conditions supporting her supplemental claim.

The Settlement Agreement provides that:

- (2) **FOR MATRIX B-1:** Diet Drug Recipients who are eligible for Matrix Compensation Benefits and to whom one or more of the following conditions apply, or their Representative Claimants, will receive Matrix Compensation Benefits determined by application of Matrix B-1, provided that such Diet Drug Recipients or Representative Claimants have registered (or are deemed to have registered) for settlement benefits by Date 2:

....

- (c) Diet Drug Recipients who ingested Pondimin® and/or Redux™ for sixty-one (61) or more days, who were diagnosed by a Qualified Physician as FDA Positive by an Echocardiogram performed between the commencement of Diet Drug use and the end of the Screening Period, with any of the following conditions....

Settlement Agreement § IV.B.2.d.(2). The plain language of this provision does not contain a temporal limitation on the existence

of the conditions that follow. We must apply the Settlement Agreement as written.

We further disagree with claimant that the phrase "with any of the following conditions" must modify "diagnosed by a Qualified Physician as FDA Positive by an Echocardiogram performed between the commencement of Diet Drug use and the end of the Screening Period." According to Ms. Haberman, the condition(s) must be present on the echocardiogram performed between the commencement of Diet Drug use and the end of the Screening Period on which claimant was diagnosed as FDA Positive. In other words, claimant reads the provision as though it were written: "Diet Drug Recipients who ingested Pondimin® and/or Redux™ for sixty-one (61) or more days, who were diagnosed with any of the following conditions and as FDA Positive by a Qualified Physician by an Echocardiogram performed between the commencement of Diet Drug use and the end of the Screening Period." We are not persuaded. The only fair reading of this provision is that the phrase "who were diagnosed by a Qualified Physician as FDA Positive by an Echocardiogram performed between the commencement of Diet Drug use and the end of the Screening Period" modifies the Diet Drug Recipients to whom the provision applies, not the timing associated with the diagnosis of a particular reduction factor.

We also reject claimant's argument that our interpretation of Section IV.B.2.c.(2) supports her view. That Section states:

- (2) **MATRIX LEVEL II** is left sided valvular heart disease with complicating factors, and is defined as:

....

- (b) Moderate MR (20% - 40% RJA/LAA) or Severe MR (>40% RJA/LAA) with one or more of the following....

Settlement Agreement § IV.B.2.c.(2). We have read this language to mean that "a claimant is entitled to Level II benefits for damage to the mitral valve if he or she is diagnosed with moderate or severe mitral regurgitation and one of five complicating factors delineated in the Settlement Agreement." PTO No. 8630 at 3 n.5 (Mar. 31, 2011). This Section, unlike Section IV.B.2.d.(2)(c), does not contain any commas or qualifying phrases between moderate or severe mitral regurgitation and "with one or more of the following." It is clear that, by the insertion of commas, the drafters intended the phrase "with any of the following conditions" to modify the phrase "Diet Drug Recipients who ingested Pondimin® and/or Redux™ for sixty-one (61) or more days."

Furthermore, we do not agree with claimant that the existence of the reduction factors delineated in the Settlement Agreement must be determined at the point when claimant first qualified for Matrix Benefits. Ms. Haberman's claim for Level III benefits did not exist until she underwent mitral valve surgery on November 9, 2009. See Settlement Agreement § IV.B.2.c.(3)(a). Upon the submission of that claim, the Trust was obligated to confirm that there was a reasonable medical

basis for Ms. Haberman's attesting physician's representations that she did not suffer from any of the reduction factors applicable to her claim.

Finally, the court rejects Ms. Haberman's assertion that she is entitled to Matrix A-1 benefits because her mitral annular calcification did not cause her mitral regurgitation or necessitate her valve surgery. Causation is not at issue in resolving Ms. Haberman's claim for Matrix Benefits. Rather, Ms. Haberman is required to prove that she meets the objective criteria set forth in the Settlement Agreement. As we previously concluded:

Class members do not have to demonstrate that their injuries were caused by ingestion of Pondimin and Redux in order to recover Matrix Compensation Benefits. Rather, the Matrices represent an objective system of compensation whereby claimants need only provide that they meet objective criteria to determine which matrix is applicable, which matrix level they qualify for and the age at which that qualification occurred....

PTO No. 1415 at 51 (Aug. 28, 2000). In addition, we noted:

... [I]ndividual issues relating to causation, injury and damage also disappear because the settlement's objective criteria provide for an objective scheme of compensation.

Id. at 97. If claimants are not required to demonstrate causation, the converse also is true, namely, in applying the terms of the Settlement Agreement, the Trust does not need to establish that a reduction factor caused the medical condition at issue. The Settlement Agreement unequivocally requires a claim

to be reduced to Matrix B-1 if the claimant has mitral annular calcification. See Settlement Agreement § IV.B.2.d.(2)(c)ii)d). We must apply the Settlement Agreement as written. Accordingly, claimant's argument that mitral annular calcification did not cause her mitral regurgitation and the need for her heart valve surgery, even if true, is irrelevant to the issue before the court.¹⁰

For the foregoing reasons, we conclude that claimant has not met her burden of proving that she is entitled to Matrix A Benefits. Therefore, we will affirm the Trust's denial of Ms. Haberman's claim for Matrix A Benefits and the related derivative claim submitted by her spouse.

10. Ms. Haberman also filed a motion to compel and to enforce PTO No. 8576 wherein she sought production of all documents sent to or from the auditing cardiologist. According to claimant, these documents are "highly relevant" because they might reveal Dr. Penkala's lack of independence. Even if a basis existed for claimant's request for additional information or her accusations relating to Dr. Penkala and the Trust, given our disposition of this claim, in which Ms. Haberman's own physician's confirmed the existence of a reduction factor, any documents claimant might obtain would have no bearing on the outcome of this proceeding. Accordingly, we will deny the motion.